



UNITED STATES PATENT AND TRADEMARK OFFICE

JUL 20 2001

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

Patricia D. Granados
Foley & Lardner
Washington Harbour, Suite 500
Washington DC 20007-5109


Re: Patent Term Extension
Application for
U.S. Patent No. 5,196,444

#25

Dear Ms. Granados:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,196,444 for a period of 413 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). For your convenience, a copy of the patent submission sample format (downloaded from FDA's internet web page) with the address for the Orange Book is enclosed.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.


Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Enclosure: Patent term extension certificate
Patent Submission Sample Format

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 98E-0839
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,196,444
(45) ISSUED : March 23, 1993
(75) INVENTORS : Takehiko Naka, et al.
(73) PATENT OWNER : Takeda Chemical Industries Ltd.
(95) PRODUCT : ATACAND® (candesartan cilexetil)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,196,444 based upon the regulatory review of the product ATACAND® (candesartan cilexetil) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 413 days

from April 18, 2011, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the Patent and Trademark Office to be affixed this 18th day of July 2001.

Nicholas P. Godici

Nicholas P. Godici

Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office